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THREE STEP-SANDWICH RIA FOR IgM CLASS ANTIBODY TO HBcAg. Dainabot Company Limited, Matsudo, Chiba, Japan.

Virus specific IgM class antibody has been detected in most acute infections and is a reliable marker for acute diseases.

The illness of patients who are infected with hepatitis B Virus (HBV) takes many different courses including subclinical illness with uneventful recovery, acute fluminant disease, and chronic forms which begin with either subclinicals or acute features.

For this reason it is often difficult to differentiate acute or recent infection from remote or chronic infection and to distinguish acute hepatitis B from non A - non B hepatitis (NANB) in a chronic carrier, despite the availability of liver function and serological tests.

We have developed a simplified 3 step-sandwich RIA for IgM to hepatitis B core antigen (HBcAg) using two kinds of monoclonal antibodies, one of them was antibody to human IgM and another was antibody to HBcAg.

Within-assay and between-assay CV's on three control serum panels were 5.2 - 13.1 % and 4.4 - 7.0 %, respectively.

These results indicate that the sandwich method with monoclonal antibodies can be useful for routine clinical applications.

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SOLID PHASE SANDWICH RADIOIMMUNOASSAY OF CEA WITH MONOCLONAL ANTIBODIES. Dainabot Company Limited, Matsudo, Chiba, Japan.

The clinical usefulness of CEA as a tumor marker has been confirmed and CEA is routinely determined for diagnosis and prognostic monitoring of cancerous diseases. The assay presented here is a sandwich RIA using two monoclonal antibodies directed to different antigenic determinants. The assay kit consists of antibody coated beads, I-125 labeled antibody, and standards (1 to 500 ng/ml), and sample volume required is 50 µl without pretreatment. First and second incubation allow 2 hours at room temperature with shaking, respectively.

The use of monoclonal antibodies yielded a decrease of cross reaction with CEA related antigens and an elimination of batch to batch variation on antibody production. Intra, inter and lot to lot assay CV's were 2.4 - 7.2 %, 4.4 - 9.9 % and 4.7 - 7.5 %, respectively. The mean recovery ratio in 5 specimens was 95.1 % on the recovery study, and the dilution test resulted in a good linearity.

These results indicate that the sandwich RIA with monoclonal antibodies is very useful for routine clinical application.

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RADIOIMMUNOASSAY OF SCC ANTIGEN FOR DIAGNOSIS OF CERVICAL SQUAMOUS CELL CARCINOMA. Dainabot Company Limited, Matsudo, Chiba, Japan.

SCC antigen (Squamous cell carcinoma related antigen) purified from cervical squamous cell carcinoma liver metastasis tissue was a protein with a molecular weight of 45,000 and the PI of 6.6. SCC antigen showed a cross reactivity with tumor antigen TA-4 which was found in cervical squamous cell carcinoma by Kato et al. However, the electrophoretic mobility of SCC antigen was different from that of TA-4, although they both have the common antigenic site. Radioimmunoassay of SCC antigen developed was based on a double antibody method and the sensitivity was less than 0.5 ng/ml by using 0.1 ml sample. On the clinical studies, ninety-five percent of healthy controls showed lower SCC antigen levels than 2 ng/ml. Fifty-one percent (121/237) of patients with cervical squamous cell carcinoma showed higher SCC antigen levels than 2 ng/ml. In 183 patients with gynecologic benign disease and other benign disease, 5 % showed false positive levels. SCC antigen also showed positive levels in the patients with squamous cell carcinoma of lung and esophagus. These results demonstrated that SCC antigen RIA was useful for the diagnosis and prognosis of cervical squamous cell carcinoma.

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AN IMMUNORADIOMETRIC ASSAY USING A NEW TUMOR MARKER OF EPITHELIAL OVARIAN CANCER. S.Choh, M.Takahashi, Y.Kazahaya, K.Isaka, and E.Hasegawa. Green Cross Corporation.

The immunization of mice with an epithelial cell line derived from an ovarian cystadenocarcinoma provides a monoclonal antibody (OC125) which recognizes a coelomic epithelium related antigen. This glycoproteic differentiation antigen has been named cancer antigen CA125. An ELISA-CA125 Kit (CIS) has been developed to detect CA125 in serum. By this kit levels of CA125 are high in patients with ovarian carcinomas and low in normal donors or most patients with benign diseases or other cancers. This kit is precise and reproducible for the quantitation of CA125 levels in human serum. Coefficients of variation for intra and inter-assay on three control serum pools were 6.1 to 14.6 %. And over the range from 6 to 500 U/ml, linear standard curves were obtained. In the recovery study approximately 99.1% of CA125 was found to be recovered. Cross reactivity against tumor markers such as CEA, AFP, CA19-9 were not found. In clinical study when cut off levels were set at 35U/ml, serum CA125 was positive in 82.7% (86/104) for ovarian carcinoma.